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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,874	03/20/2006	Sakae Tsuda	19758-002US1-OSP-18668	7504

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EXAMINER	
GEBREYESUS, KACNEW H	

ART UNIT	PAPER NUMBER
1656	

NOTIFICATION DATE	DELIVERY MODE
03/15/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/549,874	TSUDA ET AL.	
	Examiner	Art Unit	
	KAGNEW H. GEBREYESUS	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 7-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 7-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response on 1/3/2011 to the Office Action dated 10/5/2010 is acknowledged. Claims 1-3 and 7-9 are pending in the application. Claims 4-6 are cancelled. Claim 7 is currently amended. Claims 1-3 and 7-9 are presented for further consideration. Claims 1 and 7 are independent.

All objections and rejections not reiterated in the previous action are hereby withdrawn.

Priority

This Application is a 371 national stage application of international Application, PCT/JP2003/17020, filed on December 26, 2003 and claims the benefit of priority from Japanese application 2003-7897, filed on March 20, 2003. Applicants have submitted an English translation of the foreign document. Therefore priority is acknowledged for March 20, 2003.

Maintained - Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 7-9 were rejected under 35 U.S.C. 102(b) as being anticipated by Tsuda et al (WO/1998/004147 published in May 02, 1998 in IDS) as evidenced by Chao et al (Structure - function relationship in the globular type III antifreeze protein: Identification of a cluster of surface residues required for binding to ice. Protein Science Vol. 3, 10, pages 1760-1769, 1994).

Tsuda et al (WO/1998/004147) teach a process for the production of a frozen food product (the example provided is ice-cream) comprising admixing an antifreeze protein with said food product (note that ice-cream comprises water molecules and non-water molecules) thus anticipates claim 7. Furthermore claim 1 in the instant application is anticipated because inhibition of freeze concentration (as recited in claim 1) is an inherent property of the antifreeze protein on the hydrous material (ice-cream). Claims 2 and 8 are drawn to methods of inhibiting freeze concentration of a substance in a hydrous material or having a pH range of 2.0 to 11.0 (claim 2) by adding an antifreeze protein or a method of producing a frozen product or freeze-dried product by freezing or freeze drying a hydrous material having a pH range of 2.0 to 11.0 (claim 8)).

Applicants argue:

"...Applicants cannot accept these rejections since none of WO 1998/004147 (Fenn et al.), US 5,620,732 (Clemmings et al.), and US 5,118,792 (Warren et al.) discloses or suggests Applicant's method for inhibiting "freeze concentration" of a substance other than water molecules contained in a hydrous material by means of the antifreeze protein (hereinafter, referred to as "AFP"), which is disclosed in the present invention...".

Furthermore applicants argue that, it is necessary to explain that the process of freezing a hydrous Material can proceed via Process 1 or via Processes 1 and 2 described below.

> Process 1 : Natural occurrence of ice nucleation particles (single crystals of ice) and crystal growth.
>
> Process 2: Formation of lump of ice caused by "combination" of the ice nucleation particles themselves generated in Process 1.

They further state that "freeze concentration" is a phenomenon caused only by Process 2. They state that while Process 1 is a natural phenomenon which inevitably occurs during freezing, Process 2, and the "freeze concentration" associated therewith, does not inevitably occur.

Applicants further argue that it is apparent that Process 2 does not necessarily occur, and recite various technologies used in the prior art in order to purposely cause "freeze concentration".

In the first instance it should be noted that none of the technologies mentioned by applicants appear to use or mentioned any antifreeze protein for the various techniques recited in applicants argument (namely a suspension crystallization method (for example, Halde, R.; "Concentration of Impurities by Progressive Freezing," Water Research, 14, 575-580 (1979)) and a surface advance freeze concentration method (for example, A. Matsuda, K. Kawasaki, and H. Kadota; "Freeze Concentration with Supersonic Radiation under Constant Freezing Rate - Effect of Kind and Concentration of Solutes-", J. Chem. Eng. Japan, 32, 569-572 (1999)).

Furthermore Applicants argue that, a "technology for inhibiting combination of plural ice crystals" which occurs in Process 2 was completed based on the examples described in the specification of the present application as originally filed. In contrast, all of the cited references merely relate to "technologies for inhibiting growth of ice crystals" which occurs in Process 1 therefore fail to verify the effects of inhibiting Process 2. Applicants state that, since the term "freeze concentration" is not described at all in the cited references, the cited references, fail to verify the effects of inhibiting Process 2, will have effect for inhibiting not only Process 1, but also Process 2.

Applicant's argument has been considered carefully but the argument has not been found persuasive. However it should be noted that the since the applied references have reduced the method of using an antifreeze protein into practice, the references do not have to recite what the

inherent properties of the antifreeze protein in the hydrous material. By following the method steps the inherent properties of the antifreeze protein and the conditions used will be manifest. Therefore the claims remain anticipated by Tsuda et al (WO/1998/004147).

"...Applicants further state that WO 1998/004147 (Fenn et al.) relates to a process for the production of a frozen food product comprising AFP, wherein the conditions are chosen such that the ice-crystals in the product have an aspect ratio ranging from 1.1 to 1.9. In addition, US 5,620,732 (Clemmings et al.) relates to a method for minimizing ice crystal size in a frozen composition by adding AFP to a hydrous mixture. As described above, freeze concentration depends on the transfer rates of freeze surfaces or surface conditions (turbulent conditions of the surfaces), and does not directly relate to an ice crystal size or an aspect ratio of the ice crystal, as specified in the aforementioned references. Therefore, the aforementioned references fail to disclose, or to suggest, that AFP can inhibit freeze concentration..."

However these references use AFP in the process of freezing the hydrous mixture thus the inherent properties of AFP would inevitably result. These inherent properties include inhibition of "freeze concentration" and any other undisclosed properties that the AFP has.

With regards to WO 1998/004147 Applicants argue:

"... a person skilled in the art could not have conceived of the novel use of AFP of inhibiting freeze concentration of a substance other than water molecules in a hydrous material. Consequently, the rejection could only have been issued by application of impermissible hindsight by the Examiner..."

Applicant's argument has been fully considered but not found persuasive. In the first instance in response to applicant's argument that the examiner's conclusion of anticipation and/or obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily or can be a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In the instant case the claims do not add any additional product or step that can render the claimed invention patentably distinct from what has been disclosed in applied prior art references. Applicant's argument appears to be that the prior art (at least the recited references) did not disclose the inherent properties of the products used therefore the references do not anticipate the claimed invention.

However as stated above the recitation of inherent properties of a product used in the claimed method does not preclude the claimed invention from anticipation by a prior art disclosure that teaches the same method steps and the products used in the method.

"...With regards to US 5,118,792 (Warren et al.), Applicants argue US 5,118,792 (Warren et al.) relates to a fusion protein consisting essentially of a polypeptide exhibiting ice crystal growth suppression activity and a heterologous protein domain. As described above, US 5,118,792 (Warren et al.) provides "technologies for inhibiting growth of ice crystals" occurring in Process 1. Therefore, ...fail to teach, or suggest, that the AFP can inhibit freeze concentration."

However it should be noted that it is the AFP that is added to the hydrous material in the method steps disclosed in claims 1-3 and 7-9 that results in the inherent properties exhibited in a hydrous material. Thus adding an antifreeze protein to an aqueous solution under specified conditions should result in all the inherent effects of the antifreeze protein in the hydrous material. The teaching of Warren et al encompasses a methods for producing compositions comprising antifreeze polypeptides to improve freezing tolerance of organic materials such as foodstuffs and biologics, as well as protect plant products, such as during growth.

They teach that the antifreeze polypeptides assist in suppressing ice crystal growth in foodstuffs and biologics, without harming desirable aspects of the food or decreasing the viability of the biologic (thus considered to inhibit freeze concentration). They teach

introducing an antifreeze polypeptide into liquid surrounding an organ, issue or other biological sample such as for example during transportation to a hospital for a transplantation operation or for storage purposes. They also encompass using the antifreeze protein for other medically important temperature sensitive biological samples such as blood and blood products, therapeutic agents, protein drugs, bioassay reagents and vaccines (thus bioactive substances).

Among other uses, Warren et al also teach that the antifreeze polypeptides assist in suppressing ice crystal growth in foodstuffs and biologics (thus inhibit freeze concentration), without harming desirable aspects of the food or decreasing the viability of the biologic. They teach that the AFP polypeptides may also be added into foods which are expected to be frozen for example, ice cream, frozen yogurt, ice milk, sherbet, popsicles, frozen whipped cream, frozen cream pies, frozen puddings and the like. In particular, texture and flavor are adversely affected by the formation of large ice crystals throughout a freeze-thaw cycle that occurs in most home frost-free freezers or upon sustained storage in the frozen state.

It should be noted that the method steps disclosed in claims 1-3, 7-9 comprise a step of adding an antifreeze protein to a hydrous material. Thus adding an antifreeze protein to an aqueous solution under specified conditions should result in all the inherent effects of the antifreeze protein in the hydrous material.

While Warren et al do not specifically recite what the specific pH or the temperature of the hydrous material to which the antifreeze protein is admixed to, the art teaches that the activity of antifreeze proteins (e.g. type III antifreeze proteins) is optimal at pH 2 to pH 11 (see for example Chao et al). Therefore, one of skill in the art would use a pH range within the broad range of pH 2 and 11 to achieve optimum activity. Claims 3, 6 and 9 are also within the

limitation of the method taught by Warren because in at least one specific embodiment the antifreeze mixture is added to the hydrous material at room temperature and subsequently cooled. For example in a non-limiting embodiment Warren et al teach admixing a recombinant fusion antifreeze protein to a popsicle mixture comprising water, sugar, corn sweetener, citric acid, cellulose gum, guar gum, carrageenan, artificial flavors, vitamin C, artificial color, and FD&C yellow #5) where said mixture is first brought to room temperature and then the antifreeze protein is added. Furthermore example 3C teaches adding antifreeze protein to a root beer mixture at room temperature.

Therefore claims 1-3, 7-9 are anticipated by or, US 5,118,792 (Warren et al.) in view of Chao et al. absence evidence to the contrary.

Conclusion: No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

/KAGNEW H GEBREYESUS/
Examiner, Art Unit 1656
March 8, 2011.

/Manjunath N. Rao /
Supervisory Patent Examiner, Art Unit 1656